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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/078,042

02/19/2002

Donald C. Roe

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06/30/2006

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EXAMINER

KOPPIKAR, VIVEK D

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/078,042	<b>Applicant(s)</b> ROE ET AL.	
	<b>Examiner</b> Vivek D. Koppikar	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/19/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/24/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 1-13 have been examined in this application. This communication is the first action on the merits. The Information Disclosure Statement (IDS) statement filed on May 24, 2002 has also been acknowledged.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicants use the term "Quality Window" software in claim 2 and this term is a trademark which refers to a specific type of software. Trademarks, by their nature, are not necessarily permanent and may refer to many different types of goods and/or services and in addition the types of goods and/or services these trademarks refer to may change over time. Therefore, the examiner recommends amending the claims so that they recite a more generic and permanent term.

For the purposes of examination, the examiner will interpret any data analysis software that the prior art teaches to meet the limitation set forth in this claim.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-2 and 5-13 are rejected under 35 U.S.C. 102(a) as being anticipated by US Patent Number 6,319,199 to Sheehan.

(A) As per claim 1, a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

- a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);
- b) a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);
- c) at least one data analysis mechanism generating insights relevant to a particular health condition wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Sheehan: Col. 7, Ln. 4-18) (Note: In Sheehan the data analysis mechanism is a group of population analysis because the images are compared to patterns or templates stored in the memory of the data acquisition and measurement device (computer); see Sheehan (Col. 7, Ln. 7-18); and
- d) an information presentation mechanism displaying the insights relevant to the particular health condition (Sheehan: Col. 4, Ln. 54-67).

(B) As per claim 2, in the system of Sheehan the at least one data analysis mechanism further comprises data analysis software (Sheehan: Col. 2, Ln. 58-62 and Col. 7, Ln. 47-59).

(C) As per claim 5, in the system of Sheehan the at least one data measurement mechanism includes a sensor (Sheehan: Col. 1, Ln. 29-38).

(D) As per claim 6, Sheehan teaches a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition

(Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group: a tablet PC, voice recognition, and telemetry based systems (Sheehan: Col. 2, Ln. 34-46 and Col. 8, Ln. 18-32);

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Sheehan: Col. 7, Ln. 4-18); and

d) an information presentation mechanism displaying the insights relevant to the particular health condition (Sheehan: Figures 3 and 5 (220) and Col. 4, Ln. 54-67)

(E) As per claim 7, in the system of Sheehan at least one data acquisition mechanism includes a handheld device selected from the group: a PDA and a handheld PC (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32)

(F) As per claim 8, the system of Sheehan includes:

a) a data measurement mechanism generating data relevant to a particular health condition

(Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Col. 7, Ln. 4-18 and Col. 4, Ln. 54-67); and

d) an information presentation mechanism displaying the insights relevant to the particular health condition, wherein the at least one information presentation mechanism is selected from the group: a graphical summary screen, an icon based summary screen, a help guide, an anthropomorphic help guide, and synthesized speech (Sheehan: Figures 3-5; Col. 4, 54-67 and Col. 6, Ln. 47-59)

(G) As per claim 9, Sheehan teaches a method for improving the health of an individual (Sheehan: Abstract) including the steps of:

a) selecting at least one health parameter appropriate for the particular individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional (Sheehan: Col. 4, Ln. 12-18);

b) measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: Col. 2, Ln. 23-46);

c) acquiring the data for storage and subsequent analysis (Sheehan: Col. 2, Ln. 23-46);

d) analyzing the data via at least one data analysis mechanism to define out-of-control situations requiring intervention, potential causes or remedies wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Sheehan: Col. 7, Ln. 4-18);

e) presenting the information (alert) to the individual, caregiver, or medical professional (Sheehan: Col. 6, Ln. 47-59 and Col. 7, Ln. 13-19).

(H) As per claim 10, in the method of Sheehan the information presented is selected from the group: statistical analysis, out-of-control points, control rules violations, specification violations, medical limit violations, medical condition related information, advertising for products related to the individual's medical condition or health event, help guides, summary screens (Sheehan: Figures 3 and 5 (220); Col. 4, Ln. 62-68 and Col. 7, Ln. 4-18).

(I) As per claim 11, in Sheehan the system comprising a data acquisition mechanism including an image capture device for capturing a digital image of the tympanic membrane (Sheehan: Col. 4, Ln. 3-5)

(J) As per claim 12, in the system of Sheehan there is a communication device to send the digital image for analysis at a remote location (Sheehan: Col. 1, Ln. 29-53).

(K) As per claim 13, Sheehan teaches a system for managing the health of a tympanic membrane of an individual according to claim 11 further comprising:  
an otoscope having a power source and a light source (Sheehan: Figure 3; Col. 6, Ln. 12-21 and Col. 8, Ln. 27-33);  
an image acquisition tip (Sheehan: Figure 3; Col. 6, Ln. 12-21 and Col. 8, Ln. 27-33);  
a data storage mechanism (Sheehan: Col. 6, Ln. 30-32);  
a communication port selected from the group: a phone jack, a USB port, a serial port, and a parallel port (Sheehan: Col. 8, Ln. 24-31); and  
an image capture mechanism selected from the group: a CCD image sensor, a CMOS image sensor, a digital camera, and a color board camera (Sheehan: Col. 1, Ln. 29-53).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan, as applied to Claim 1, above, and in further view of US Patent Number 5,920,478 to Ekblad.

(A) As per claim 3, Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performance, however, this feature is taught by Ekblad (Col. 11, Ln. 52-59). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Ekblad with the motivation of having a means of allowing adaptive updating in response to changes (variations) in data, as recited in Ekblad (Col. 11, Ln. 52-59). In the alternative, the examiner takes Official Notice that this feature is well known in the art and at the time of the invention one of ordinary skill in the art would have been motivated to have modified the system of Sheehan with this aforementioned feature with the motivation of having a means to set the control limits so that they reflected and were up to date to changes in the raw historical performance data that was obtained from various patients.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan, as applied to Claim 1, above, and in further view of US Patent Number 6,642,592 to Loman.



(A) As per claim 4, Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration, however, this feature is taught by Loman (Col. 5, Ln. 14-16). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Loman with the motivation of having a fault resolution means (Loman: Col. 10-14) to detect faults and failures within the system of Sheehan.

### *Conclusion*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Number 6,936,007 to Quay teaches a method and apparatus for health and disease management combining patient data monitoring with wireless internet connectivity.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone number for this group is (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available

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through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely, 

Vivek Koppikar

3/8/2006

  
C. LUKE GRELLIGAN  
PATENT EXAMINER